

(1996). For the reasons set forth in this Opinion, this Court find as follows with respect to the two disputed claim terms: (1) “inhaler for inhaling powdered pharmaceutical compositions from capsules” is limiting; and (2) “proximate” means “near or close to.”

I. BACKGROUND

A. Factual Background

This case arises out of an action for patent infringement instituted by Boehringer against Lupin. Boehringer is a German company with subsidiaries incorporated in Germany, Switzerland, and the state of Delaware. (ECF No. 1 ¶¶ 3-6.) Lupin is an Indian company with a subsidiary incorporated in Switzerland. (*Id.* ¶¶ 6-8.) Boehringer manufactures and sells SPIRIVA® HandiHaler® (“product” or “inhaler”) for the purpose of treating bronchospasm associated with chronic obstructive pulmonary disease (“COPD”). (*Id.* ¶ 18.)

On April 13, 2010, the United States Patent and Trademark Office (“USPTO”) lawfully issued the ’676 patent entitled “Dry Powder Inhaler.” (*Id.* ¶ 23.) The first claim term at issue appears in the preamble of the ’676 Patent, which states the patent is directed to “[a]n inhaler for inhaling powdered pharmaceutical compositions from capsules.” (*Id.* at 57-58.) The second claim term at issue appears in Claims 1 and 13 of the ’676 patent and specifies the location of the gripping aid as “disposed *proximate to* an edge of the mouthpiece and *proximate to* the actuating member when the mouthpiece is closed.” (*Id.* at 58.) Additionally, the chart below sets forth the parties’ proposed constructions.

| Claim Language | Asserted Claims | Boehringer Construction | Lupin Construction |
|--|------------------------|--|-------------------------------|
| “inhaler for powdered pharmaceutical compositions from capsules” | ’676 Claims 1, 13 | Preamble term is limiting, does not require further construction | Preamble term is not limiting |

| | | | |
|--|-------------------|---|--|
| | | | If it is limiting, should be construed as “inhalation device” |
| “gripping aid disposed proximate to an edge of the mouthpiece and proximate to the actuating member when the mouthpiece is closed” | ’676 Claims 1, 13 | “gripping aid located close to an edge of the mouthpiece and close to the actuating member when the mouthpiece is closed” | “gripping aid disposed next to or immediately before/after an edge of the mouthpiece and next to or immediately before/after the actuating member when the mouthpiece is closed” |

B. Procedural History

On August 10, 2018, Boehringer filed a Complaint asserting claims of infringement against Lupin. (ECF No. 1.) On October 30, 2018, Lupin filed an Answer to the Complaint along with counterclaims asserting the noninfringement and invalidity of the patents-in-suit. (ECF No. 23.)

On November 6, 2019, both Boehringer and Lupin filed their opening *Markman* briefs. (ECF Nos. 76 & 77.) On December 16, 2019, both Boehringer and Lupin filed their *Markman* reply briefs. (ECF Nos. 80 & 81.) On March 11, 2020, this Court held a *Markman* hearing, at the conclusion of which this Court ordered supplemental briefing on the disputed claim terms. (ECF No. 90.) On March 23, 2020, the parties simultaneously submitted supplemental claim construction briefs. (ECF Nos. 91 & 92.)

II. LEGAL STANDARD

Claims define the scope of the inventor’s right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope and is a determination reserved exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (*en banc*). Indeed, the court can only

interpret claims and “can neither broaden nor narrow claims to give the patentee something different than what it has set forth” in the specification. *E.I. Du Pont de Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1998). A court’s determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman v. Westview Instruments*, 52 F.3d 967, 986 (Fed. Cir. 1995) (*en banc*), *aff’d*, *Markman*, 517 U.S. 370 (holding that “[t]he focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean”); *Phillips*, 415 F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (e.g., expert reports and testimony). *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

The analysis of claim language begins with determining the “ordinary and customary meaning of a claim term[, which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. Further, the language should not be read solely in the context of the claim under review; instead, it should be analyzed “in the context of the entire patent” and with an understanding of how that language is used in the field from which the patent comes. *Id.* In conducting this review, a different interpretation is placed on a term located in an

independent claim than on those located in dependent claims, and it is understood that each claim covers different subject matter. *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1315 (holding that the “presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim”))).

In reviewing the language of a patent, “the court starts the decision-making process by reviewing the same resources as would [a person or ordinary skill in the art in question], viz., the patent specifications and the prosecution history.” *Phillips*, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). When “the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent,” understanding claim construction “involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. “In such circumstances, general purpose dictionaries may be helpful” to explain the terms used. *Id.*

Often times, however, the ordinary meaning of the claim language is not readily apparent, and in such circumstances, courts look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* Those sources may include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* Furthermore, claims must be read in view of the claim specification, which is of seminal importance in providing framework for understanding the claim language. As the Federal Circuit in *Markman* explained:

The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define

terms used in the claims. As we have often stated, a patentee is free to use his [or her] own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and the purpose of the claims.

Markman, 52 F.3d at 979-80.

This Court's reliance on the specification is appropriate given the Patent and Trademark Office's rules requiring "that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent bases in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'" *Phillips*, 415 F.3d at 1316-17 (quoting 37 C.F.R. § 1.75(d)(1)). During this analysis, however, courts should not "import limitations from the specifications into the claims." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005)).

The patent's prosecution history is also of "primary significance in understanding the claims." *Markman*, 52 F.3d at 980. "The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. Further, the prosecution history is also relevant to determining whether the patentee disclaimed or disavowed the subject matter, thereby narrowing the scope of the claim terms. *Seachange Int'l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005).²

² "[I]n certain cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect

In addition to intrinsic evidence, a court may also rely on extrinsic evidence in interpreting a claim. *Phillips*, 415 F.3d at 1317. Extrinsic evidence consists of “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Id.* (citations omitted). However, while extrinsic evidence “can shed useful light on the relevant art,” it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* Extrinsic evidence should be “considered in the context of intrinsic evidence,” as there are flaws inherent in the exclusive reliance on extrinsic evidence, including, *inter alia*, biases, inadvertent alterations of meanings, and erroneous contextual translations. *Id.* at 1318-19. Furthermore, extrinsic evidence should not be relied upon where “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

to the patentee’s intent to disavow a broader claim scope. *Ventana*, 473 F.3d at 1181 (citing *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319-20 (Fed. Cir. 2006); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342-44 (Fed. Cir. 2001)). However, pointing solely to “general statements by the [patentee] indicating that the invention is intended to improve upon prior art” will not demonstrate that the patentee intended to “disclaim every feature of every prior art device discussed in the ‘BACKGROUND ART’ section of the patent.” *Ventana*, 473 F.3d at 1181; *see also Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (“Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.”) Moreover, the Federal Circuit has found it “particularly important not to limit claim scope based on statements made during prosecution ‘[a]bsent a clear disavowal or contrary definition.’” *Digital Vending Servs. Int’l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1273 (Fed. Cir. 2012) (citing *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed. Cir. 2011) (quoting *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004))). The reason for such a stringent rule is “because the prosecution history represents an ongoing negotiation between the PTO and the application,” and “it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Digital Vending*, 672 F.3d at 1273 (quoting *Phillips*, 415 F.3d at 1317).

III. DECISION

This Court addresses the interpretation of the two disputed terms in the '676 patent—“inhaler for inhaling powdered pharmaceutical compositions from capsules” and “proximate to”—in turn.

A. The Meaning of “inhaler for inhaling powdered pharmaceutical compositions from capsules”

Boehringer proposes that the preamble term “inhaler for inhaling powdered pharmaceutical compositions from capsules” is limiting and does not require further construction (ECF No. 77 at 9) whereas Lupin proposes the preamble term is not limiting or, if it is limiting, it should be construed as “inhalation device.” (ECF No. 76 at 9.)

Boehringer contends the preamble term is limiting here because it provides antecedent basis for the body of the claims and discloses a fundamental characteristic of the invention. (ECF No. 77 at 11-12.) Specifically, Boehringer argues the preamble term provides antecedent basis for the terms “the capsule” and “the capsules.” (*Id.* at 11.) However, Lupin argues the preamble term is simply an introduction to the body of the claims. (ECF No. 76 at 11.)

Whether to treat a preamble as a limitation is “determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history.” *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed. Cir. 1996). In general, a preamble is limiting if it is “‘necessary to give life, meaning, and vitality’ to the claim.” *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (quoting *Kropa v. Robie*, 187 F.2d 150, 152, 38 C.C.P.A. 858, 1951 Dec. Comm’r Pat. 177 (CCPA 1951)).

In *Catalina Marketing International, Inc. v. Coolsavings. com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002), the Federal Circuit identified several guideposts to determine whether a preamble

acts as a claim limitation. Specifically, “when reciting additional structure . . . underscored as important by the specification, the preamble may operate as a claim limitation.” *Id.* at 808. Additionally, a preamble phrase that provides antecedent basis for a claim limitation generally limits the scope of the claim. *Id.* at 808; *Bell Commc’ns Research, Inc. v. Vitalink Commc’ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995). However, if the body of the claim describes a structurally complete invention, a preamble is not limiting where it “merely gives a name” to the invention, extols its features or benefits, or describes a use for the invention. *Catalina*, 289 F.3d at 809.

Here, the preamble term is necessary to understand the claimed invention. The ’676 Patent is replete with references to dry powder inhalers and the specification addresses a concern specific to dry powder inhalers—“ensur[ing] quick and reliable opening” for “patients who would otherwise find it difficult to use” an inhaler that requires repeated reloading. Additionally, the specification discloses improvements to the inhaler recited in the preamble. In sum, the specification underscores the importance of the preamble term as a limitation of the claimed invention as the preamble.

Additionally, the preamble term provides antecedent basis for the terms “the capsule” and “the capsules.” Indeed, the use of “the” preceding “capsule” and “capsules” signals reliance on the preamble term for antecedent basis. *See, e.g. In re Ciprodex*, No. 15-5756, 2017 WL 2784410, at *8 (D.N.J. June 27, 2017) (“[I]t is widely understood that the recitation of the term ‘the’ or ‘said’ before a feature indicates to a reader that the feature following these terms has been introduced prior in the claim language.”). Despite Lupin’s contentions, the term “capsule holder” does not supply antecedent basis for “the capsule” or “the capsules.” Primarily, the presence of an intervening term alone does not mean the intervening term provides antecedent basis for a claim

term that follows.³ Indeed, only the preamble specifies the particular type of capsule used—one with “powdered pharmaceutical compositions.” Therefore, it is necessary to give meaning to the structure of a “capsule holder for receiving the capsules.”

In arguing the preamble term is not limiting, Lupin relies on *Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320 (Fed. Cir. 2019). That ruling is inapposite. Chiefly, the preamble in *Arctic Cat* provided no antecedent basis for the claims and instead merely recited an intended use. As stated above, the preamble term in the '676 Patent provides antecedent basis for “the capsule” and “the capsules.” In many cases, antecedent basis alone demonstrates that a preamble term is limiting.⁴ Therefore, because the preamble term provides antecedent basis and is necessary to understand the invention, the preamble is limiting.

For the reasons stated above, the Court finds the preamble term, “inhaler for inhaling powdered pharmaceutical compositions from capsules” is limiting.

B. The Meaning of “proximate to”

Boehringer proposes that “proximate to” be construed to have its ordinary meaning (ECF No. 77 at 15) whereas Lupin proposes that “proximate to” be construed to mean “next to or immediately before/after.” (ECF No. 76 at 14.)

³ See, e.g., *Bondyopadhyay v. United States*, 748 F. App'x 301, 303–06 (Fed. Cir. 2018) (“geodesic sphere phased array antenna system” preceded by “a geodesic structure,” “plurality of said geodesic planar surfaces each having mounted thereon a subarray of planar antenna element units,” and other similar terms); *Kinzenbaw v. Case, LLC*, 318 F. Supp. 2d 778, 789 (N.D. Iowa 2004), *aff'd*, 179 F. App'x 20 (Fed. Cir. 2006) (“tractor” preceded by “tractor hitch”); *Microstrategy Inc. v. Bus. Objects Americas*, 410 F. Supp. 2d 348, 357 (D. Del. 2006), *aff'd*, 238 F. App'x 605 (Fed. Cir. 2007) (“users” preceded by “network user interface”).

⁴ See, e.g., *In re Ciprodex*, 2017 WL 2784410, at *8; *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, No. 11-3962, at *2 (D.N.J. Apr. 22, 2015); *Bed Bath & Beyond Inc. v. Sears Brands, LLC*, No. 08-5839, at *7 (D.N.J. Oct. 22, 2010).

Because the '676 Patent does not explicitly define “proximate,” the term carries its plain and ordinary meaning as understood by one of ordinary skill in the art. *See Philips*, 415 F.3d at 1313. Courts have routinely ruled that the plain meaning of “proximate to” is “at or near,” rather than “next to.”⁵ As such, Lupin’s proposed construction of proximate as “next to” does not comport with the plain meaning of “proximate.”

In addition to their above argument, Lupin contends their proposed construction is appropriate because the claim language instructs the gripping aid must be in direct contact with the edge of the mouthpiece and the actuating member. (ECF No. 76 at 16.) This, also, does not comport. As Boehringer demonstrated at the *Markman* hearing, the gripping aid is not in direct contact with the actuator. Additionally, Boehringer cleared up confusion by noting the “edge of the mouthpiece” was the bottom edge of the entire mouthpiece. As stated in the *Markman* hearing:

MR. SIPES: The edge of the mouthpiece is the body here. This, this ridge, that's the gripping aid. That's not the edge of the mouthpiece.

THE COURT: Okay. Now, for purposes of the record, counsel is indicating that if we go to Diagram -- page 35, gripping aid. I think that's on --

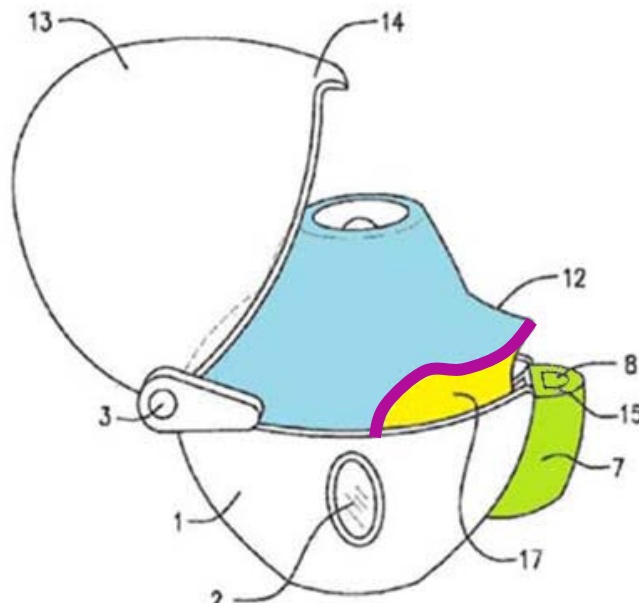
⁵ *See, e.g., Izzo Golf, Inc. v. Taylor Made Golf Co.*, No. 04-6253, 2008 WL 2559370, at *7–8 (W.D.N.Y. June 23, 2008) (construing “proximate the second location” as “at or near the second location,” rejecting more restrictive construction of “at or immediately adjacent to the second location”); *One World Techs., Ltd. v. Rexon Indus. Corp.*, No. 04-4337, 2005 WL 1377897, at *5 (N.D. Ill. June 3, 2005) (construing “proximate the region of the cut” as “next to or very near” the region, but not “at the area of the cut”); *180s, Inc. v. Gordini U.S.A., Inc.*, 699 F. Supp. 2d 714, 725 (D. Md. 2010) (construing “disposed proximate” as “located closely in space [to]” rather than “near and within”); *Comput. Stores Nw., Inc. v. Dunwell Tech, Inc.*, No. 10-284, 2011 WL 2160931, at *40 (D. Or. May 31, 2011) (construing “proximate” as “near or by” rather than “abutted against or in close proximity”); *Kinzenbaw v. Case, LLC*, 318 F. Supp. 2d 778, 811 (N.D. Iowa 2004) (construing “proximate” as “very near” or “close”) (Fed. Cir. 2006).

MR. SIPES: If we go to Slide 49 of their slides, Your Honor, what they've highlighted in purple might be a way of referencing it.

THE COURT: Okay. I thought it was 35.

MR. SIPES: If we see in the middle column '676 gripping aid, you'll see what they've highlighted in purple . . .What they've done here in purple, that's the ridge that is part of the gripping aid itself. That's how you grip the mouthpiece to lift it up. I think my colleague on the other side used her fingernail under that ridge to lift it up. I used my finger, but it's clearly the gripping aid. The edge of the mouthpiece is the very bottom of that mouthpiece and that's the edge of the mouthpiece. After all, the gripping aid can't be itself defining the edge of the mouthpiece because it's part of the mouthpiece. And that purple highlighted ridge that they have is part of the gripping aid.

(ECF No. 90 (Unofficial Transcript of March 11, 2020 *Markman* Hearing) at 76:24-78:17.)



(ECF No. 92-1 at 35.)

The above graphic illustrates Boehringer's argument. Based in part on the above, the Court rejects Lupin's contention that the "edge of the mouthpiece" needs to be touching both the gripping aid and actuating member.

Finally, Lupin contends the term "proximate" was used to mean "touching" during the prosecution of the '676 Patent. (ECF No. 76 at 19.) Specifically, Lupin argues that, because Boehringer added the "proximate" language to distinguish its patent from the prior art, "proximate" must mean the edge of the mouthpiece is next to the gripping aid. (*Id.*) However, Boehringer's addition of "proximate" was only used to distinguish from the prior art and dictated simply the gripping aid be "close to" the mouthpiece edge and the actuator. (*See* ECF No. 91-1 at 58) ("The examiner rejected over an inhaler that, according to the examiner, had a gripping aid because the lid could be opened by catching a finger on the curvature of the mouthpiece."). Nowhere in the prosecution of the '676 Patent did Boehringer limit the meaning of "proximate" to require touching. Therefore, the prosecution of the '676 Patent did not change the meaning of "proximate."

For the reasons stated above, the Court construes "proximate" to have its plain and ordinary meaning, which is "near or close to."

IV. CONCLUSION

For the reasons set forth above, this Court find as follows with respect to the two disputed claim terms: (1) "inhaler for inhaling powdered pharmaceutical compositions from capsules" is limiting; and (2) "proximate" means "near or close to."

Date: April 16, 2020

/s/ *Brian R. Martinotti*
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE